K011675

Special 510(k): Device Modification Summary of Safety and Effectiveness

JUN 2 2 2001

Proprietary Name
The AUTOTAC System™

Common Name
Screw, tack, membrane fixation pin

Classification Name
Intraosseous fixation screw

Classification
Class II

Official Contact
BioHorizons Implant Systems, Inc.
One Perimeter Park South
Suite 230 South
Birmingham, AL 35243
(205) 967-7880
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Device Description

The AUTOTAC System™ consists of components and instruments designed to fixate and stabilize bioresorbable and non-bioresorbable barrier membranes used for regeneration of tissue and/or bone in the oral cavity or in other clinical situations that require membrane use/fixation. The system provides an anchoring mechanism for the membranes to resident and adjacent bone or tissue at the surgical site. The Tissue Tack is fabricated from a well-known bioresorbable polymer and has a round, flat head, and two circular ribs on the shaft to prevent the implanted tack from slipping out. The tack is provided sterile by either gamma or ETO sterilization and is not intended to be re-sterilized by the user.

Product Evaluation

The AUTOTAC System™ tissue tack was evaluated by consulting clinicians and laboratory studies and found to be effective for fixation of barrier membranes without new health risks and is a predictable means to achieve clinical success in guided bone and/or tissue regeneration.

Mechanical tests demonstrated that the pull-out and shear strength of the AUTOTAC System™ tissue tack is sufficient to prevent premature movement of the periodontal membrane.

Indications for Use

The AUTOTAC System™ is intended to fixate and stabilize bioresorbable and non-bioresorbable barrier membranes used for regeneration of tissue in the oral cavity or in other clinical situations that require membrane use/fixation.

Substantial Equivalence Information

The AUTOTAC System™ ETO-sterilized tissue tack is substantially equivalent to all features which could affect safety or effectiveness to the gamma-sterilized tissue tack (K993493) due to the similarities in tack design, material and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 2 2001

Mr. Donald E. Dalton
Director of Quality Assurance
Biohorizons Implant Systems, Incorporated
One Perimeter Park South, Suite 230, South
Birmingham, Alabama 35243

Re: K011675
Trade/Device Name: The Autotac System
Regulation Number: 872.4880
Regulatory Class: II
Product Code: DZL
Dated: May 29 ,2001
Received: May 30, 2001

Dear Mr. Dalton:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note:

this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K011675

Device Name: The AUTOTAC System™

Indications for Use:

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PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K011675

Prescription Use ✓ OR Over-the-Counter Use _____
(per 21 CFR 801.109)